

JAN 12 2004

Roche ONLINE Quinidine Assay

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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1) Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd. Indianapolis, IN 46250 (317) 845-2000 Contact Person: Mike Flis Date Prepared: July 28, 2003
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2) Device name	Roche ONLINE TDM Quinidine
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3) Predicate device	We claim substantial equivalence to the Roche COBAS INTEGRA Quinidine [K951595].
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4) Device Description	The assay is a homogeneous immunoassay based on the principle of measuring changes in scattered light or absorbance which result when activated microparticles aggregate. The microparticles are coated with quinidine and rapidly aggregate in the presence of a quinidine antibody solution. When a sample containing quinidine is introduced, the aggregation reaction is partially inhibited, slowing the rate of the aggregation process. Antibody bound to sample drug is no longer available to promote microparticle aggregation, and subsequent particle lattice formulation is inhibited. Thus, a classic inhibition curve with respect to quinidine concentration is obtained, with the maximum rate of aggregation at the lowest quinidine concentration. By monitoring the change in scattered light or absorbance, a concentration-dependent curve is obtained.
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510(k) Summary, Continued

5) Intended use For the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers.

6) Comparison to predicate device The Roche ONLINE TDM Quinidine was evaluated for several performance characteristics, including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche ONLINE TDM Quinidine is substantially equivalent to the currently marketed Roche COBAS INTEGRA Quinidine Assay. The following table presents the precision and method comparison results.

Roche ONLINE TDM Quinidine				Roche COBAS INTEGRA Quinidine, (Predicate labeling)		
Versus Roche COBAS INTEGRA Quinidine Assay (predicate device) N = 150 Y = 1.054X - 0.036 R = 0.991 Range = 0.22 to 7.04 µg/mL				Versus Enzyme Immunoassay N = 154 Y = 0.941X - 0.024 R = 0.991 Range = 0.16 to 5.7 µg/mL		
NCCLS	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Precision:						
Mean (µg/mL)	0.93	2.87	4.61	1.35	3.47	5.42
CV% (within run)	2.0	1.3	1.2	2.1	2.2	2.0
CV% (total)	3.9	2.7	2.7	3.2	3.5	3.2



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 12 2004

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, In 46250-0457

Re: k032332
Trade/Device Name: Roche ONLINE TDM Quinidine Assay
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: LBZ
Dated: October 31, 2003
Received: November 4, 2003

Dear Mr. Flis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

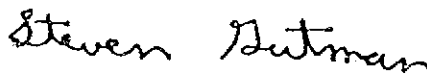
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Roche Diagnostics Corporation

510(k) Number (if known):

Device Name: Roche ONLINE TDM Quinidine Assay

Indications for Use:

The Roche ONLINE TDM Quinidine assay is for the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers. Quinidine is used for the prevention and treatment of ventricular arrhythmias, junctional (nodal) arrhythmias, and supraventricular (atrial) arrhythmias. The quinidine dosage required to achieve therapeutic serum levels is dependent on the drug formulation, patient age, and individual variability in absorption and metabolism. The proposed labeling indicates the Roche/Hitachi 911, 912, 917, and Modular P analyzers can be used with the Roche ONLINE Quinidine reagent kits.

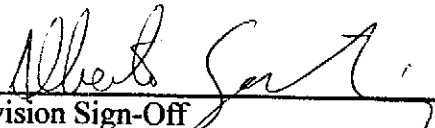
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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



Division Sign-Off

(Optional Format 1-2-96)

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k032332